



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:  
Khosravi, et al.  
Serial No:  
10/092,769  
Filed:  
March 7, 2002  
For:  
INSULIN-LIKE GROWTH FACTOR  
SYSTEM AND CANCER

§  
§ Group Art Unit: 1642  
§ Examiner: Unknown  
§

Commissioner For Patents  
Washington, D.C. 20231

Dear Sir:

In compliance with the duty of disclosure under 37 CFR §1.56, and in accordance with the practice under 37 CFR §1.97 and §1.98, the Examiner's attention is directed to the documents listed on the enclosed modified Form PTO-1449. No inference should be made that the cited references are in fact material, are in fact prior art, or that no better art exists. The cited patents are listed in numerical order and are not in any order based on their pertinence. Copies of the listed information are attached.

This Information Disclosure Statement is being filed within three months of the United States filing date or before the mailing date of a first Office Action on the merits. No certification or fee is required (37 CFR §1.97(b)).

The Commissioner is hereby authorized to charge any additional fees which may be required or credit any overpayment to Deposit Account 08-1394.

It is respectfully requested that the above information be considered by the Examiner and that a copy of the enclosed Form PTO-1449 be returned indicating that such information has been considered.

Respectfully submitted,

Brian J. Hubbard  
Reg. No. 45,873

Date: April 30, 2002  
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D-1015838.1

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I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to Commissioner For Patents, Washington, D.C. 20231 on April 30, 2002.

SANDRA KUBIN

Printed Name

Signature

<p>In place of PTO-1449 Form</p> <p style="text-align: center;">MAY 06 2002 <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <small>(use as many sheets as necessary)</small></p>				Complete if Known	
				Application Number	10/092,769
				Filing Date	March 7, 2002
				Applicant(s)	Khosravi, et al.
				Art Unit	1642
				Examiner Name	Unknown
				SHEET	1

U. S. PATENT DOCUMENTS				
Examiner's Initials	Cite No.	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
	A1	5,614,372	03-25-1997	Lilja, et al.

FOREIGN PATENT DOCUMENTS					
Examiner's Initials	Cite No.	Foreign Patent Document (Country Code - Number - Kind)	Publication Date MM-DD-YYYY	Patentee or Applicant of Cited Document	Translation Y/N
	B1	WO 96/26442	08-29 1996	Lilja, et al.	
	B2	EP 0 811 164 B1	01-09-2002	Lilja, et al.	

OTHER PRIOR ART		
Examiner's Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article, title of the item, date, page(s), volume-issue number(s), publisher, city/country where published
	C1	Albanes, "Total Calories, Body Weight, and Tumor Incidence in Mice", Cancer Research 47: 1987-1992 (April 15, 1987)
	C2	Andersson et al., "Body Size and Prostate Cancer: a 20-year Follow-up Study Among 135006 Swedish Construction Workers", J. National. Cancer Institute, 89(5) 385-389-9 (1997) Abstract Only.
	C3	Aquilina et al., "Androgen Deprivation as a Strategy for Prostate Cancer Chemoprevention", J. Natl. Cancer Institute, 89(10): 689-696 (1997) Abstract Only.
	C4	Arteaga et al., "Blockade of the Type I Somatomedin Receptor Inhibits Growth of Human Breast Cancer Cells in Athymic Mice", J. Clin. Invest., Vol. 84: 1418-1423 (November 1989)
	C5	Avila et al., "Sequence Determination of Variable Region Genes of Two Human Monoclonal Antibodies Against <i>Neisseria meningitidis</i> ", Gene 92), 127: 237-274 (1993)
	C6	Azmi et al., "Variable Region Sequences and Idiotypic Expression of a Protective Human Immunoglobulin M Antibody to Capsular Polysaccharides of <i>Neisseria meningitidis</i> Group B and <i>Escherichia coli</i> K1", Infection and Immunity, 62(5): 1776-1786 (May 1994)
	C7	Barni et al., "Serum Levels of Insulin-Like Growth Factor-I in Operable Breast Cancer in Relation to the Main Prognostic Variables and Their Perioperative Changes in Relation to Those of Prolactin", Tumori, 80: 212-215 (1994)
	C8	Bates et al., "Mammary Cancer in Transgenic Mice Expressing Insulin-Like Growth Factor II (IGF-II), British Journal of Cancer, 72: 1189-1193 (1995)
	C9	Boyle et al., "Geographical and Temporal Patterns of Incidence and Mortality From Prostate Cancer", Urology, 46(3 Suppl. A): 47-55 (1995) Abstract Only.
	C10	Bruning et al., "Insulin-like Growth-Factor-Binding Protein 3 Decreased in Early-Stage Operable Pre-Menopausal Breast Cancer, Int'l. J. Cancer, 62: 266-270 (1995)
	C11	Campagnoli et al., "Differential Effects of Oral Conjugated Estrogens and Transdermal Estradiol on Insulin-Like Growth Factor 1, Growth Hormone and Sex Hormone Binding Globulin Serum Levels", Gynecol. Endocrinol., 7: 251-258 (1993)

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C12	Canobbio et al., "Somatuline (BIM 23014) and Tamoxifen Treatment of Postmenopausal Breast Cancer Patients: Clinical Activity and Effect on Insulin-Like Growth Factor-I (IGF-I) Levels", Anticancer Res. 15(6B): 2687-2690 (November-December 1995)
C13	Chen, et al., "Co-Expression of Bovine Growth Hormone (GH) and Human GH Antagonist Genes in Transgenic Mice", Endocrinology, 138(2): 851-854 (1997)
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C22	Finne et al., "Insulin-Like Growth Factor I is Not a Useful Marker of Prostate Cancer in Men with Elevated Levels of Prostate-Specific Antigen", The Journal of Clinical Endocrinology & Metabolism, 85(8): 2744-2747 (2000)
C23	Friedl et al., "Suppression of Serum Insulin-Like Growth Factor-I Levels in Breast Cancer Patients During Adjuvant Tamoxifen Therapy", Eur. J. Cancer, 29A(10): 1368-1372 (1993)
C24	Frost et al., "Changes in the Insulin-Like Growth Factor (IGF), Insulin-Like Growth Factor Binding Protein (IGFBP) & IGFBP Protease Status with Endocrine Therapy for Breast Cancer", Journal of Endocrinology, Vol. 139: 102 (1993)
C25	Gann et al., "Prospective Study of Sex Hormone Levels and Risk of Prostate Cancer", J. Natl. Cancer Institute, 88(16): 1118-1126 (1996) Abstract Only.
C26	Gann et al., "A Prospective Evaluation of Plasma Prostate-Specific Antigen for Detection of Prostatic Cancer", JAMA 273(4): 289-294 (1995) Abstract Only.
C27	Giovannucci et al., "The CAG Repeat Within the Androgen Receptor Gene and Its Relationship to Prostate Cancer", Proc. Natl. Acad Sci USA, 94(15): 8272 (1997) Abstract Only.

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	C28	Goodman-Gruen et al., "Epidemiology of Insulin-Like Growth Factor-I in Elderly Men and Women. The Rancho Bernardo Study", Am. J. Epidemiol., 146(4): 357 (1997) Abstract Only.
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	C31	Hankinson, et al., "Alcohol, Height and Adiposity in Relation to Estrogen and Prolactin Levels in Postmenopausal Women", Journal of the National Cancer Institute, 87(17): 1297-1302 (September 6, 1995)
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	C38	Hsing et al., "Regulation of Apoptosis Induced by Transforming Growth Factor-Beta 1 in Nontumorigenic Rat Prostatic Epithelial Cell Lines", Cancer Research, 56(22): 5146-5149 (1996) Abstract Only.
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C43	Huynh et al., "Estradiol and Antiestrogens Regulate a Growth Inhibitory Insulin-Like Growth Factor Binding Protein 3 Autocrine Loop in Human Breast Cancer Cells", The Journal of Biological Chemistry, 271(2): 1016-1021 (1996).
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C47	Jones et al., "Insulin-Like Growth Factors and Their Binding Proteins: Biological Actions", Endocrine Reviews, 16(1): 3-34 (1995)
C48	Juul et al., "Serum Insulin-Like Growth Factor-I in 1030 Healthy Children, Adolescents, and Adults: Relation to Age, Sex, Stage of Puberty, Testicular Size, and Body Mass Index", J. Of Clinical Endocrinology and Metabolism, 78(3): 744-752 (1994)
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C55	Lassarre et al., "Serum Insulin-Like Growth Factors and Insulin-Like Growth Factor Binding Proteins in the Human Fetus. Relationships with Growth in Normal Subjects with Intrauterine Growth Retardation", Pediatric Res., 29(3): 219-225 (1991) Abstract Only.
C56	La Vecchia et al., "Height and Cancer Risk in a Network of Case-Control Studies From Northern Italy, " Interrogatory. J. Cancer, 45(2): 275-279 (1990) Abstract Only.
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SHEET 5 OF 8

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C58	Lee et al., "Insulin-Like Growth Factors and Breast Cancer", Biomedicine & Pharmacotherapy, 49(9): 415-421 (1995)
C59	Lee et al., "IGF System Components as Prognostic Markers in Breast Cancer", Breast Cancer Research and Treatment, Vol. 47: 295-302 (1998)
C60	Lonning et al., "Influence of Tamoxifen on Plasma Levels of Insulin-Like Growth Factor I and Insulin-Like Growth Factor Binding Protein I in Breast Cancer Patients", Cancer Research 52: 4719-4723 (September 1, 1992)
C61	Lonning et al., "Relations Between Sex Hormones, Sex Hormone Binding Globulin, Insulin-Like Growth Factor-I and Insulin-Like Growth Factor Binding Protein-1 in Post-Menopausal Breast Cancer Patients", Clinical Endocrinology, 42(1): 23-30 (1995)
C62	Lucas et al., "Age-Dependent V Region Expression in the Human Antibody Response to the <i>Haemophilus influenzae</i> Type b Polysaccharide", The Journal of Immunology, 150(5): 2056-2061, No. 1.5 (March 1, 1993)
C63	Malaab et al., "Direct Effects of Tamoxifen on Growth Hormone Secretion by Pituitary Cells <i>in vitro</i> ", Eur. J. Cancer, 28A(45): 788-793 (1992)
C64	Mantzoros et al., "Insulin-Like Growth Factor 1 in Relation to Prostate Cancer and Benign Prostatic Hyperplasia", British Journal of Cancer, 76(9): 1115-1118 (1997)
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C68	Miglietta et al., "Suramin and Serum Insulin-Like Growth Factor Levels in Metastatic Cancer Patients", Anticancer Research, 13:2473-2476 (1993).
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C70	Oh et al., "Transforming Growth Factor $\beta$ -Induced Cell Growth Inhibition in Human Breast Cancer Cells in Mediated Through Insulin-Like Growth Factor-Binding Protein-3 Action", The Journal of Biological Chemistry, 270(23): 13589-13592 (1995)
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C72	Osorio et al., "Insulin-Like Growth Factors (IGFs) and IGF binding proteins-1, -2, and -3 in Newborn Serum: Relationships to Fetal Placental Growth at Term", Early Human Development 46: 15-26 (1996)
C73	Papa et al., "Insulin-Like Growth Factor-I Receptors are Overexpressed and Predict a Low Risk in Human Breast Cancer", Cancer Res., 53(16): 3736-3740 (August 15, 1993)

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C75	Parrillo, "The Effect of Low-Dose Warfarin on the Risk of Stroke in Patients with NonRheumatic Atrial Fibrillation", The New England Journal of Medicine, 323(22): 1560-1562 (November 29, 1990)
C76	Peyrat et al., "Insulin-Like Growth Factor 1 Receptors (IGF1-R) and IGF1 in Human Breast Tumors", J. Steroid Biochem. Molec. Biol., 37(6): 823-827 (1990)
C77	Peyrat, et al., "Plasma Insulin-Like Growth Factor-1 (IGF-1) Concentrations in Human Breast Cancer", Eur. J. Cancer, 29A(4): 492-497 (1993)
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C84	Pollak et al., "Relationship of Circulating Insulin-Like Growth Factor I Level to Breast Cancer Risk", 4 <sup>th</sup> International Symposium on Insulin-Like Growth Factors, C29 (1997)
C85	Pollak, "Endocrine Effects of IGF-I on Normal and Transformed Breast Epithelial Cells: Potential Relevance to Strategies for Breast Cancer Treatment and Prevention", Breast Cancer Research and Treatment, 47: 209-217 (1998)
C86	"Prostate Cancer: Progress in Screening, Prevention Holds Promise", Harvard Health Letter, 23(9): 4-5 (1998)
C87	Rasmussen et al., "Paracrine/Autocrine Regulation of Breast Cancer by the Insulin-Like Growth Factors", Breast Cancer Research and Treatment, 47: 219-233 (1998)
C88	Rechler, "Editorial: Growth Inhibition by Insulin-Like Growth Factor (IGF) Binding Protein-3 – What's IGF Got To Do With It?", Endocrinology, 138(7): 2645-2647 (1997)
C89	Rocha et al., "Levels of Insulin-Like Growth Factor Binding Protein 3 (BP3) and its mRNA Correlate in Human Breast Cancer", Breast Cancer Research and Treatment, 32: 57 (1994)

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C90	Rocha et al., "Insulin-Like Growth Factor Binding Protein-3 (IGFBP3) and Insulin Receptor Substrate (IRS1) in Primary Breast Cancer: Larger Tumors Have Higher BP3 Levels and Higher Levels of IRS1 are Associated with Lower Disease-Free Survival (DFS) rate", <i>Breast Cancer Research and Treatment</i> , 37: 55 (1996)
C91	Rosner, "Multivariate Methods in Ophthalmology with Application to Other Paired-Data Situations", <i>Biometrics</i> 40: 1025-1035 (December 1984)
C92	Rozen et al., "Antiproliferative Action of Vitamin D-Related Compounds and Insulin-Like Growth Factor-Binding Protein 5 Accumulation", <i>Journal of the National Cancer Institute</i> , 89(9): 652-656 (May 7, 1997)
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C94	Ruan et al., "Estradiol Enhances the Stimulatory Effect of Insulin-Like Growth Factor-I (IGF-I) on Mammary Development and Growth Hormone-Induced IGF-I Messenger Ribonucleic Acid", <i>Endocrinology</i> 136(3): 1296-1302 (1995)
C95	Rudman et al., "Effects of Human Growth Hormone in Men Over 60 Years Old", <i>N. Engl. J. Med.</i> , 323(1): 1-6 (1990) Abstract Only
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C97	Sepp-Lorenzino, "Structure and Function of the Insulin-Like Growth Factor I Receptor", <i>Breast Cancer Research and Treatment</i> , 47: 235-253 (1998)
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C99	Sinha et al., "Serum Pituitary and Urine Concentrations of Prolactin and Growth Hormone in Eight Strains of Mice with Varying Incidence of Mammary Tumors", <i>Int'l. J. Cancer</i> , 24: 430-437 (1979)
C100	Surmacz et al., "Type I Insulin-Like Growth Factor Receptor Function in Breast Cancer", <i>Breast Cancer Research and Treatment</i> , Vol. 47: 255-267 (1998)
C101	Tennant, et al., "Changes in the Insulin-Like Growth Factor System in Prostate Cancer", <i>J. Investigational Med.</i> 44(1): 154A (1996) Abstract only
C102	Thissen et al., "Nutritional Regulation of the Insulin-Like Growth Factors", <i>Endocrine Reviews</i> , 15(1): 80-101 (February 1994)
C103	Tibblin et al., "High Birthweight as a Predictor of Prostate Cancer Risk", <i>Epidemiology</i> , 6(4): 423-424 (1995) Abstract
C104	Tornell et al., "Induction of Mammary Adenocarcinomas in Metallothionein Promoter-Human Growth Hormone Transgenic Mice", <i>Int'l. J. Cancer</i> , 49: 114-117 (1991)

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				Filing Date	March 7, 2002
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				Art Unit	1642
				Examiner Name	Unknown
SHEET	8	OF	8	Attorney Docket Number	28758.65

	C105	Tornell et al., "High Frequency of Mammary Adenocarcinomas in Metallothionein Promoter-Human Growth Hormone Transgenic Mice Created from Two Different Strains of Mice", J. Steroid Biochem. Molec. Biol., 43(1-3): 237-242 (1992)
	C106	Toropainen et al., "Expression of Insulin-Like Growth Factor I (IGF-I) in Female Breast Cancer as Related to Established Prognostic Factors and Long-term Prognosis", Eur. J. Cancer, 31A(9): 1443-1448 (1995)
	C107	Toropainen et al., "Expression of Insulin-Like Growth Factor II in Female Breast Cancer as Related to Established Prognostic Factors and Long-Term Prognosis", Anticancer Res., 15(6B): 2669-2674 (November-December 1995)
	C108	Torrisi et al., "Effects of the Synthetic Retinoid Fenretinide (4-HPR) in Plasma Levels of Insulin-Like Growth Factor (IGF-I) in Breast Cancer Patients", Breast Cancer Research and Treatment, 27(1-2): 185 (1993)
	C109	Ware, "Growth Factors and Their Receptors as Determinants in the Proliferation and Metastasis of Human Prostate Cancer", Cancer and Metastasis Reviews, 12: 287-301 (1993)
	C110	Woods et al., "Brief Report: Intrauterine Growth Retardation and Postnatal Growth Failure Associate with Deletion of the Insulin-Like Growth Factor I Gene (Original Articles)", New England Journal of Medicine, 335(18): 1363-1367 (1996)
	C111	Yang et al., "Reduced Growth of Human Breast Cancer Xenografts in Hosts Homozygous for the <i>lif</i> Mutation", Cancer Research 56, 1509-1511 (April 1, 1996)
	C112	Yee et al., "Prognostic Significance of Insulin-Like Growth Factor-Binding Protein Expression in Axillary Lymph Node-Negative Breast Cancer", Journal of the National Cancer Institute, 86(23): 1785-1789 (December 7, 1994)
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	C117	Zarandi et al., "Synthesis and Biological Activities of Highly Potent Antagonists of Growth Hormone-Releasing Hormone", Proc. Natl. Acad. Sci. USA, 91: 12298-12302 (December 1994).

Examiner Signature		Date Considered
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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include a copy of this form with next communication to applicant.